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AstraZeneca

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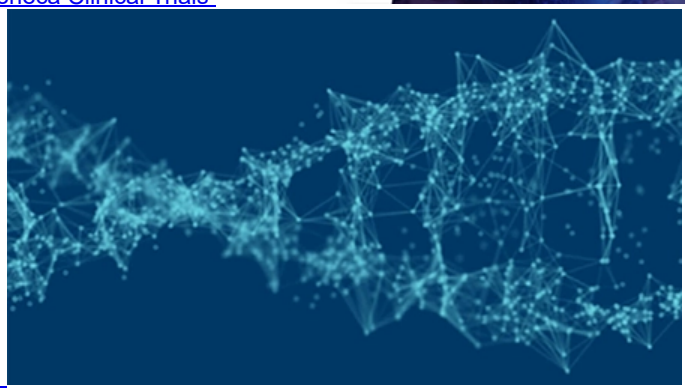
Featured website AstraZeneca Clinical Trials Featured website Open Innovation 

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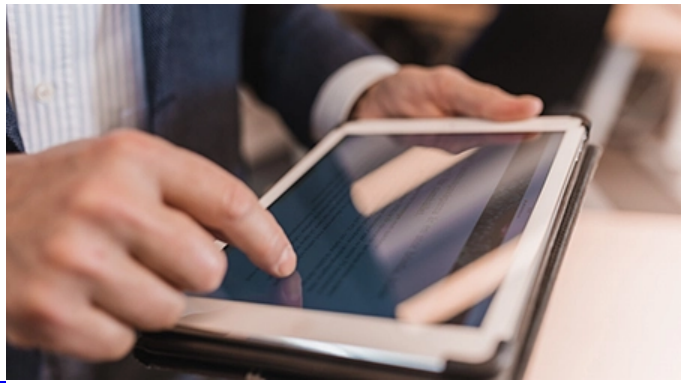

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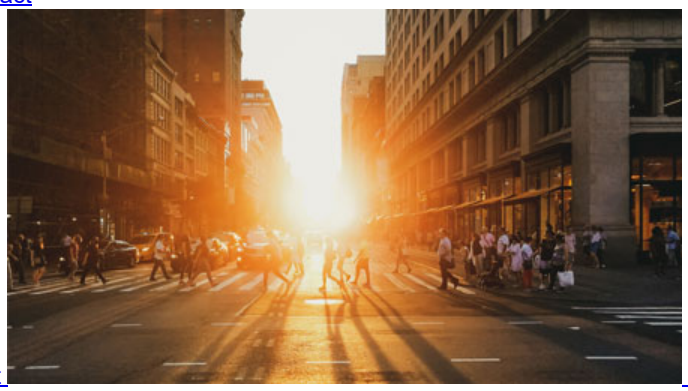

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COVID-19 Long-Acting AntiBody (LAAB) combination AZD7442 rapidly advances into Phase III clinical trials

PUBLISHED 9 October 2020

9 October 2020 21:30 BST

Two trials of AZD7442 will enrol over 6,000 adults for the prevention of COVID-19 with additional trials enrolling ~4,000 adults for the treatment of SARS-CoV-2 infections

US Government to invest ~$486m for development and supply of up to 100,000 doses and can acquire another one million doses

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AstraZeneca's long-acting antibody (LAAB) combination, AZD7442, will advance into two Phase III clinical trials in more than 6,000 participants at sites in and outside the US that are due to begin in the next weeks. The LAABs have been engineered with AstraZeneca's proprietary half-life extension technology to increase the durability of the therapy for six to 12 months following a single administration. The combination of two LAABs is also designed to reduce the risk of resistance developed by the SARS-CoV-2 virus.

The Company has received support of around $486m from the US Government for the development and supply of AZD7442 under an agreement with the Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response at the US Department of Health and Human Services, and the Department of Defense Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense.

One trial will evaluate the safety and efficacy of AZD7442 to prevent infection for up to 12 months, in approximately 5,000 participants. The second trial will evaluate post-exposure prophylaxis and pre-emptive treatment in approximately 1,100 participants.

AstraZeneca is planning additional trials to evaluate AZD7442 in approximately 4,000 patients for the treatment of COVID-19.

AstraZeneca plans to supply up to 100,000 doses starting towards the end of 2020 and the US Government can acquire up to an additional one million doses in 2021 under a separate agreement.

Pascal Soriot, Chief Executive Officer, said: "This agreement with the US Government will help accelerate the development of our long-acting antibody combination which has the potential to provide immediate and long-lasting effect in both preventing and treating COVID-19 infections. We will be evaluating the LAAB combination in different settings from prophylaxis, to outpatient treatment to hospitalisation, with a focus on helping the most vulnerable people."

LAABs mimic natural antibodies and have the potential to treat and prevent disease progression in patients already infected with the virus, as well as to be given as a preventative intervention prior to exposure to the virus. A LAAB combination could be complementary to vaccines as a prophylactic agent, e.g. for people for whom a vaccine may not be appropriate or to provide added protection for high-risk populations. It could also be used to treat people who have been infected.

Today's agreement builds on previous funding of more than $25m from US government agencies BARDA and the Defense Advanced Research Projects Agency for the discovery and evaluation of the monoclonal antibodies, as well as the Phase I clinical trial started in August 2020[1] to assess safety, tolerability and pharmacokinetics of AZD7442 in healthy individuals.

Financial considerations
The agreement is not anticipated to impact the Company's financial guidance for 2020 as the US Government funding is being offset by expenses to progress the clinical trials of AZD7442 as well as manufacturing process and upscaling costs. Should the Phase III trials prove successful and AZD7442 become an approved medicine, the Company anticipates providing the medicine at commercial terms during and after the current coronavirus pandemic.

AZD7442
AZD7442 is a combination of two LAABs derived from convalescent patients after SARS-CoV-2 infection. Discovered by Vanderbilt University Medical Center and licensed to AstraZeneca in June 2020, the LAABs were optimised by AstraZeneca with half-life extension and reduced Fc receptor binding. The half-life extended LAABs should afford six to 12 months of protection from COVID-19.[2-5] The reduced Fc receptor binding aims to minimise the risk of antibody-dependent enhancement of disease - a phenomenon in which virus-specific antibodies promote, rather than inhibit, infection and/or disease.[6]

In a recent *Nature* publication, the LAABs were shown in pre-clinical experiments to block the binding of the SARS-CoV-2 virus to host cells and protect against infection in cell and animal models of disease.[7]

AstraZeneca
AstraZeneca (LSE/STO/Nasdaq: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas - Oncology, Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. Please visit astrazeneca.com and follow the Company on Twitter @AstraZeneca.

Contacts
For details on how to contact the Investor Relations Team, please click here. For Media contacts, click here.

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Adrian Kemp
Company Secretary
AstraZeneca PLC

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